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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/240,410	01/29/99	MICHALOVICH D	SP-3039

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RATNER & PRESTIA
P O BOX 980
SUITE 301 - ONE WESTLAKES (BERWYN)
VALLEY FORGE PA 19482-0980

EXAMINER	
GRASER, J	
ART UNIT	**PAPER NUMBER**
1641	9

DATE MAILED: 08/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/240,410	Michalovich et al.
Examiner	**Group Art Unit**
Graser, Jennifer	1641

☒ Responsive to communication(s) filed on *Election 7/14/99* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-12* is/are pending in the application.

Of the above, claim(s) *1, 3-5, 9, and 12* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2, 6-8, 10, and 11* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group II, claims 2, 6-8, 10 and 11) in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1, 3-5, 9 and 12 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. A certified copy of European Patent Application NO. 98300694.1 has been received.

Information Disclosure Statement

3. The information disclosure statement filed 4/19/99 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there are no publication dates on the PTO-1449 form. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2, 6-8, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite due to the phrases "at least 95% identity to the polypeptide of SEQ ID NO:2" and "at least 95% identity to that of SEQ ID NO:1" because the specific algorithm used to calculate the percent sequence identity is not disclosed in the specification. The use of terms such as percent homology, percent similarity and percent identity in connection with a recited nucleic acid or amino acid sequence is vague and indefinite in the absence of a clear description or definition of what the term means. Sequence identity between two sequences has no common meaning within the art. Without a clear and unambiguous description of how to do a comparison the metes and bounds cannot be determined.

Additionally, claim 2 part (I), (iii) and (iv) are vague and indefinite for the phrase "a sequence encoding". Said phrase should be changed to "a sequence which encodes".

Part (vi) of claim 2 is vague and indefinite because it is unclear what is meant by "stringent conditions". Are these "high stringency" conditions?

Part (vii) of claim 2 is vague and indefinite because it is unclear what is encompassed by the term "complementary". Does this mean the sequence is "fully complementary" or do Applicants intend to allow for just a few polynucleotide sequences to be complementary, i.e., one strand shorter than the other? Additionally, it is unclear what is meant by "the RNA equivalent of a polynucleotide of (I) to (vi)".

Claim 2 and dependent claims thereof are rejected because of the following informalities: said claims are not written in proper Markush form, i.e., claim 2 does not recite (v), (vi) **and** (vii) (refer to M.P.E.P 803.02). Appropriate correction is required.

Claim 6 refers to a non-elected claim and should be re-written in independent form. Additionally, claim 6 is vague and indefinite because of the phrase "capable of". Having the capability is not the same thing as actually performing the function. A positive recitation of the function is required.

Claim 11 is indefinite due to the phrases "at least 95% identity to SEQ ID NO:3" and "at least 95% identity to the amino acid sequence of SEQ ID NO:4" because the specific algorithm used to calculate the percent sequence identity is not disclosed in the specification. The use of terms such as percent homology, percent similarity and percent identity in connection with a recited nucleic acid or amino acid sequence is vague and indefinite in the absence of a clear description or definition of what the term means. Sequence identity between two sequences has no common meaning within the art. Without a clear and unambiguous description of how to do a comparison the metes and bounds cannot be determined.

The word "isolated" should be inserted after "(c) " of claim 11.

In claim 11, part (d), the phrase "sequence encoding a polypeptide" should be changed to "a sequence which encodes a polypeptide".

Claim 11 is rejected because of the following informalities: said claims are not written in proper Markush form, i.e., claim 2 does not recite (a), (b), (c) **and** (d) (refer to M.P.E.P 803.02). Appropriate correction is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2, 6-8, 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabled for polynucleotides which are "at least 95% identity to the polypeptide of SEQ ID NO:2", "at least 95% identity to that of SEQ ID NO:1" , "at least 95% identity to SEQ ID NO:3" and "at least 95% identity to the amino acid sequence of SEQ ID NO:4" because it is unclear to one skilled in the art what sequences are embraced by the claim since the specification lacks the algorithm and parameters used to determine percent identity. If it is unclear to one skilled in the art what sequences are embraced by a claim which is based on a specification which lacks the algorithm and parameters used to determine percent

homology/identity/similarity, the specification is non-enabling, since one skilled in the art would not be able to make and use those sequences without undue experimentation.

Additionally, claims 6-8 and 10 are drawn to expression vectors and host cells for producing a polypeptide; however not all of the polynucleotide sequences recited in instant claim 2 will have the ability to produce a polypeptide. Parts (ii) and (vi) of claim 2 refer to polynucleotide fragments that are less than that of SEQ ID NO:1. The polynucleotide recited in part (vi) of claim 2 reads on sequences consisting of just a few nucleotides. The specification provides no guidance as to what nucleotides may be changed without causing a detrimental effect to the protein to be produced. It is unpredictable as to which nucleotides can be removed and which could be added. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where the amino acid substitutions can b made with a reasonable expectation of success are limited. Other positions are critical to the protein's structure/function relationship, e.g., such as various positions or regions directly involved in binding, catalysis in providing the correct three-dimensional spacial orientation of binding and catalytic sites. These regions can tolerate only very little or no substitutions. Given the lack of guidance contained in the specification and the unpredictability for determining acceptable nucleotide substitutions, one of skill in the art could not make or use the invention without undue experimentation.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals (1991 Catalog, page 557), Stratagene (1991 Product Catalog, page 66), Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/93 Catalog, pages 90-91) or New England Biolabs (Catalog 1986/1987, pages 60-62).

Claim 2, part (vi), is drawn to "an isolated polynucleotide obtainable by screening a library under stringent hybridization conditions with a labeled probe having the sequence of SEQ ID NO:1 or a fragment thereof".

Boehringer Mannheim Biochemicals (1991 Catalog, page 557) and Stratagene (1991 Product Catalog, page 66) teach kits containing isolated, packaged, random 6-mer primers and random 9-mer primers. The random primer kits contain all possible 6-mer and 9-mer sequences for priming DNA sequences for labeling. The instant claims does not limit the size of the hybridizing strands.

Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/93 Catalog, pages 90-91) or New England Biolabs (Catalog 1986/1987, pages 60-62) each teach a wide variety of probes, primers and linkers.

The random primers, probes and linkers anticipate the instant claim because the instant claim does not limit the size of the hybridizing strands. Thus, the following random primers, probes and linkers are deemed to meet the limitations of hybridizing under low or high stringency conditions.

10. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Ensser et al., (Genbank Accession No. AF030698, Submitted 10/21/97).

Ensser et al. disclose a nucleotide sequence which displays an overall 99.7% match to that of Applicants' SEQ ID NO:1.

10. No claims are allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1641 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM. Please note that the name of the Examiner of record has changed from Jennifer Shaver to Jennifer Graser.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J Graser 8/9/99

JENNIFER GRASER
PATENT EXAMINER